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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

SAFEWAY INC; WALGREEN CO.; THE KROGER CO.; NEW ALBERTSON'S, INC.; AMERICAN SALES COMPANY, INC.; AND HEB GROCERY COMPANY, LP,

Plaintiffs,

vs.

ABBOTT LABORATORIES,

Defendant.

CASE NO. CV 07-5470 (CW)

Related per December 5, 2007 Order to Case No. CV 04-1511 (CW)

PRETRIAL BRIEF OF ABBOTT LABORATORIES

Judge: **Honorable Claudia Wilken**
Date: **February 28, 2011**
Time: **8:30 a.m.**
Location: **Courtroom 2 (4th Floor)**

SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, Plaintiff, vs. ABBOTT LABORATORIES, Defendant.	CASE NO. CV 07-5702 (CW) *Related per November 19, 2007 Order to Case No. CV 04-1511(CW)*
RITE AID CORPORATION; RITE AID HDQTRS CORP.; JCG (PJC) USA, LLC; MAXI DRUG, INC D/B/A BROOKS PHARMACY; ECKERD CORPORATION; CVS PHARMACY, INC.; AND CAREMARK LLC, Plaintiffs, vs. ABBOTT LABORATORIES, Defendant.	CASE NO. CV 07-6120 (CW) *Related per December 5, 2007 Order to Case No. CV 04-1511 (CW)*
MEIJER, INC. & MEIJER DISTRIBUTION, INC.; ROCHESTER DRUG CO-OPERATIVE, INC.; AND LOUISIANA WHOLESALE DRUG COMPANY, INC., ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED, Plaintiffs, vs. ABBOTT LABORATORIES, Defendant.	CASE NO. CV 07-5985 (CW) (Consolidated Cases) *Related per November 30, 2007 Order to Case No. CV 04-1511 (CW)*

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I. INTRODUCTION

After years of litigation, the Court will finally hear directly from Abbott's witnesses, who will explain first-hand why they increased the daily price of Norvir® from $1.71 to $8.57 in December 2003. These witnesses will testify—consistent with contemporaneous business documents and financial records—that they acted to align the price of Abbott's patented Norvir with its increasingly popular use as a PI booster. The antitrust laws permit Abbott to charge a monopoly price for Norvir. Nonetheless, Abbott's new daily price of $8.57 kept Norvir's place as one of the lowest-priced HIV drugs. By contrast, most other HIV drugs cost $20 to $30 a day.

This Court has granted summary judgment to Abbott on Plaintiffs' (direct purchasers and GSK) antitrust challenge to Abbott's raising the price of its patented Norvir to increase profits on sales of that drug. Such conduct is lawful and *pro*competitive. Plaintiffs' remaining antirust claim alleges that Abbott raised Norvir's price while it kept Kaletra's price constant illegally to maintain a purported "monopoly" for its boosted PI Kaletra®. According to Plaintiffs, the differential between Norvir's new price and Kaletra's price is so small that it essentially forced HIV patients to take Kaletra instead of rival PIs that are boosted by Norvir.

The first major hole in Plaintiffs' case is that doctors and HIV patients do *not* make prescription decisions based on drug prices. Patients do not pay the lion's share of drug prices; insurance companies do. Physicians prescribe what is best for their HIV patients to treat this life-threatening illness—period. For these reasons, the Norvir repricing did not have any significant effect on prescribing decisions, and Kaletra's market share continued its steady decline after that repricing.

As Abbott will demonstrate at trial, Plaintiffs cannot come anywhere close to proving their alleged Sherman Act § 2 violation. Nor will GSK prove that Abbott's pricing conduct breached the parties' ritonavir license agreement, much less that this breach violated North Carolina's Unfair and Deceptive Trade Practices Act ("UDTPA") and caused lost profits. The direct purchasers also have no damages. It is well established that, in the short run, purchasers benefit from alleged predatory pricing. But the short-run is all that is at issue in this case; everyone agrees that Kaletra has now lost any monopoly power it allegedly once had; no competitor was driven out of the market. We know

of no analogous case in which purchasers have recovered for alleged below-cost pricing or a refusal to deal.

Antitrust Claims. Plaintiffs cannot prove an antitrust violation. *First*, far from having a "monopoly" or being "dangerously close" to obtaining one, Kaletra has been getting killed by competitors. Reyataz, a PI sold by Bristol-Myers Squibb ("BMS"), was Kaletra's main competitive threat before Norvir's repricing in December 2003. Plaintiffs claim Abbott used the Norvir repricing increase to "exclude" Reyataz from the market and, thus, pave the way for supracompetitive prices for Kaletra. But the exact opposite happened. Reyataz not only remained a fierce competitor—along with seven other PIs—but it has now replaced Kaletra as the leading PI by a substantial margin. To this day, Kaletra continues to lose market share to both new and old competitors. No court has ever found or upheld a jury determination that a product has a "monopoly" when it is not even the market leader, and for good reason: A monopolist is capable of charging supracompetitive prices only because it has the power to restrict market-wide supply. That is impossible when competitors control most of the market.

Second, marketplace events refute Plaintiffs' claim of "exclusionary" conduct. This is conduct that *excludes* other companies from meaningfully competing, thus enabling the monopolist to restrict market-wide output and charge supracompetitive prices. To prove this element, Plaintiffs must show that Abbott engaged in exclusionary conduct that was anticompetitive and not justified by legitimate business reasons. They cannot meet this burden. No competitor has been forced from the market and there can be no showing that there was any other change in the market as a result of the Norvir repricing.

The evidence will show that Abbott's pricing conduct satisfies the safe harbor adopted for bundled discounting in *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883 (9th Cir. 2008). As Abbott's experts will explain, Abbott's "imputed" price for lopinavir is *above* its cost, thus barring Plaintiffs' theory of predatory pricing. Nor can Plaintiffs prove a refusal to deal under *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), especially as that case has been limited

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in the twenty-five years since it was decided.[1] According to Plaintiffs, Abbott made Norvir too expensive and thus unavailable to boost Abbott's competitors' PIs—purportedly forcing patients to buy Kaletra. But far from being unavailable, Norvir's sales have more than quintupled since the price increase. Thus, there simply has been no refusal to deal. And even if Plaintiffs could show below-cost bundled discounting or a refusal to deal, they have no evidence to rebut the legal presumption based on Abbott's patent rights that raising Norvir's price was *procompetitive*. *See Image Tech. Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997).

Finally, Plaintiffs cannot show that Abbott's pricing conduct caused antitrust injury. There is no evidence that any HIV patient who wanted Norvir was unable to get it because of its new price. On the contrary, the price in the government payor channel (more than 50% of the market) actually declined. And Abbott implemented a program to give the drug away for free to anyone else if price became an issue. Further, even if there were proof that some boosted PI demand had been switched from competitors' products to Kaletra, that would show only that the direct purchasers saved money by purchasing a less expensive alternative product, not that they were overcharged. The Direct Purchasers will be unable to prove supracompetitive prices. Nor will GSK prove that the wholesale price difference between Kaletra and the Lexiva-Norvir combination adversely affected Lexiva sales. This explains why Plaintiffs' damages calculations are wholly speculative and inflated.

GSK's Contract Claim. GSK also cannot prove its claims for breach of contract. GSK alleges that Abbott's pricing breached the parties' license agreement, which authorized GSK to promote its PI (e.g., Lexiva) with Norvir despite Abbott's patents covering Norvir's use as a PI-booster. According to GSK, however, this routine patent license implicitly constrained Abbott's ability to price Norvir as it saw fit. This is also the sole remaining allegation underlying GSK's claim for treble damages under the UDTPA.

The evidence will show that GSK received precisely what it bargained for. It continuously promoted boosted Lexiva worldwide since Lexiva's launch, resulting in significant profits that would have been impossible absent a license. Abbott *never* promised to constrain Norvir's price—

[1] Abbott's position is that both of Plaintiffs' theories fail as a matter of law, for reasons previously briefed. This brief is based on the assumption that the Court will adhere to its contrary rulings.

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expressly or implicitly. Indeed, the negotiators will testify uniformly that the parties intentionally *avoided* reaching such a promise because they are competitors and they were trained to avoid agreeing with other companies on pricing. For this reason alone, no reasonable party could assume that Abbott implicitly promised to limit Norvir's price, as GSK alleges. GSK is left with no claim.

Ultimately, Plaintiffs will not be able to identify a single patient who actually switched from a rival PI to Kaletra because of Norvir's price. This omission confirms what was obvious to Abbott when it made the pricing decisions at issue in this case—price does not influence PI prescriptions and, therefore, the Norvir price increase would have no effect on Kaletra sales. Abbott simply set a price for Norvir that reflected the enormous value of that drug.

II. PLAINTIFFS CANNOT PROVE THEIR ANTITRUST CLAIMS.

Plaintiffs make much of the size of the Norvir price increase, but Abbott is "entitled to [charge] monopoly prices on its patented" drug. *Image Tech*, 125 F.3d at 1225. To reconcile the competing interests of the patent and antitrust laws, the jury must *presume* that Abbott's justification for "[r]e-pricing Norvir"—i.e., it "will align the clinical and financial value of the product"—is legitimate and does not violate the antitrust laws. (Stockinger Decl., Ex. 98 at 7 (NOR 00096557).) To paraphrase the Ninth Circuit, "[Abbott] may assert that its desire to profit from its intellectual property rights justifies its conduct, *and the jury should presume that this justification is legitimately procompetitive*." *Image Tech*, 125 F.3d at 1219 (emphasis added).

To overcome this presumption, Plaintiffs carry the heavy burden of showing that Abbott's "business justification [for the price increase] *played no part* in the decision to act." *Id.* (emphasis added). In other words, Plaintiffs' antitrust claims necessarily fail unless they prove that Abbott increased Norvir's price *solely* to monopolize the market for Kaletra. Further, overcoming this hurdle is merely a small part of Plaintiffs' overall burden to prove its alleged Sherman Act violation.

To prove monopolization, Plaintiffs must show that Abbott (1) has monopoly power in the market in which Kaletra competes; and (2) willfully acquired or maintained monopoly power in the market for Kaletra through predatory pricing or a refusal to deal in the absence of a legitimate business justification. To prove attempted monopolization, Plaintiffs must show that Abbott (1) acted with a specific intent to monopolize the market in which Kaletra competes; (2) engaged in

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anticompetitive conduct directed at accomplishing that purpose; and (3) has a dangerous probability of achieving monopoly power in the market for Kaletra. To recover damages, Plaintiffs must also prove antitrust injury, i.e., that its loss measured to a degree of reasonable certainty flows from anticompetitive effects of Abbott's behavior. (*See* 1/14/11 Order at 10-11 (Docket No. 262).)

Plaintiffs cannot prove any, much less all, of these elements of their monopolization and attempted monopolization claims.[2]

A. Plaintiffs Cannot Show That Abbott Has Monopoly Power.

"Monopoly power is 'the power to control prices or exclude competition.'" (1/14/11 Order at 11 (citations omitted).) Plaintiffs cannot meet their burden of showing either direct or circumstantial evidence of monopoly power.

1. Plaintiffs Have No Direct Evidence Of Monopoly Power.

"Direct proof of market power may be shown by evidence of restricted output and supracompetitive prices." (1/14/11 Order at 12 (citation omitted).) As this Court explained, "[t]o prove monopoly power directly, supracompetitive pricing *must* be accompanied by restricted output. . . . *Both are required* to prove monopoly power directly." (*Id.* at 13 (emphasis added).) Plaintiffs can show no "direct evidence" of any ability by Abbott to restrict marketwide output.

The Court also stated in the summary judgment context that "[m]onopoly power may be shown directly through evidence of 'injury to competition which a competitor with market power may inflict,' which in turn demonstrates 'the actual exercise of market power.'" (*Id.* at 12.) With respect, this is an incorrect legal standard. We know of no other court that has applied this standard, and it is inconsistent with Ninth Circuit law.

Direct evidence is "evidence that is explicit and requires no inferences to establish the proposition or conclusion being asserted." *In re Citric Acid Litig.*, 191 F.3d 1090, 1094 (9th Cir.

[2] Plaintiffs have represented that this "is not a case about the acquisition of monopoly power" but instead about "maintenance of [Abbott's] monopoly power." (*See* DP Opp. to MSJ at 1; *see also* Stockinger Decl., Ex. 111 (5/5/10 Noll Rebuttal Rep. at 31 (arguing that Kaletra lost monopoly power more slowly than it would have but for the Norvir repricing)).) This shows that the theory of attempted monopoly has no place in this case. In any event, the impediments to Plaintiffs' showing monopoly power—especially Abbott's consistently declining market share—also preclude a finding of a dangerous probability of Abbott attaining monopoly power.

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1999) (quotation omitted). Monopoly power is defined by restricted output and supracompetitive pricing. A monopoly "exists when one firm controls all or the bulk of a product's output, and no other firm can enter the market, or expand output, at comparable costs" such that the "monopolist has the power to raise price above competitive levels by restricting its output, because the output reduction cannot be offset by expanded output by others." IIB Areeda & Hovenkamp, Antitrust Law ¶ 403a, at 7 (3d ed. 2007). Because this is what defines monopoly, direct evidence of monopoly power—i.e., evidence that is explicit and requires no inference—is evidence that the defendant actually restricted output and raised prices above competitive levels. *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995) ("If the plaintiff puts forth *evidence of restricted output and supracompetitive prices, that is direct proof* of the injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power.") (emphasis added); *Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1475 (9th Cir. 1997) ("Direct proof of market power may be shown by evidence of restricted output and supracompetitive prices. Such a showing is direct proof of the injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power.") (quotation and citation omitted); *accord Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007) ("The existence of monopoly power may be proven through direct evidence of supracompetitive prices and restricted output."); *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (en banc) (same); *Coastal Fuels of Puerto Rico, Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196-97 (1st Cir. 1996) (same).

The Ninth Circuit's decision in *Forsyth*—the very decision on which this Court relied for the idea that there are other forms of direct evidence of monopoly power—shows that the idea is flawed. In *Forsyth*, the Ninth Circuit held there was no direct proof of monopoly power even as it acknowledged that there was evidence the defendant had taken steps to "limit[] competition." 114 F.3d at 1476, 1478. Absent proof of "higher prices" and an "accompanying showing of restricted output," the Ninth Circuit concluded that there was no direct evidence of monopoly power. *Id*. at 1476. Similarly, in *Rebel Oil*, the defendant's pricing allegedly eliminated 37 competitors and reduced the plaintiffs' market share by 20%. 51 F.3d at 1431-32. The Ninth Circuit nevertheless held as a matter of law that there was insufficient evidence of monopoly power. *Id*. at 1443. The

decision in *Rebel Oil* would be inexplicable if the defendant's pricing and the resulting elimination of competition constituted direct evidence of monopoly power.

In short, neither *Forsyth* nor *Rebel Oil* suggests that anything less than proof of restricted output and supracompetitive prices can qualify as direct evidence of monopoly power. Indeed, both decisions make clear that evidence of purported "injury to competition" is not direct evidence of monopoly power. Here, Plaintiffs have no actual evidence that Abbott's conduct *in the market for Kaletra* could be taken only by a firm with monopoly power. Any proof of monopoly power in that market, therefore, must come from circumstantial evidence.

2. Plaintiffs Have No Circumstantial Evidence That Abbott Has Monopoly Power, Or A Dangerous Probability Of Obtaining Such Power.

To demonstrate circumstantial evidence of monopoly power, Plaintiffs must prove: (1) the market in which Kaletra competes is limited to boosted PIs, (2) Abbott has a dominant share of that market, *and* (3) there are significant barriers to entry and "existing competitors lack the capacity to increase their output in the short run." (1/14/11 Order at 15.) Plaintiffs have improperly defined the relevant product market. But Abbott has no monopoly power under *any* possible market definition, particularly considering that Kaletra is not even the market leader.

a. The Relevant Product Market In Which Kaletra Competes Is Not Limited To Boosted PIs.

Plaintiffs have not properly defined the relevant product market. This is a fatal flaw because "[w]ithout a proper definition of the relevant market, it is impossible to determine a party's influence over that market." *Kodak*, 125 F.3d at 1203 (citing *Rebel Oil*, 51 F.3d at 1434). In determining this definition, "[c]ourts consider whether the product and its substitutes are reasonably interchangeable by consumers for the same purpose, as well as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." (1/14/11 Order at 15 (quotation omitted).)

Unless the relevant market covering Kaletra is defined to include no other products (in which case Plaintiffs' antitrust claims fail because there can be no anticompetitive effect in such a market),

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that market must be defined to include *at least* all HIV drugs that form the HIV cocktail "anchor." These drugs include all PIs (including Kaletra, all boosted PIs with Norvir, and all standalone PIs) *plus* non-nucleotide reverse transcriptase inhibitors ("NNRTIs"). Anchors are generally combined with other HIV drugs called nucleotide reverse transcriptase inhibitors ("NRTIs"), which form the backbone of the HIV cocktail therapy. There are currently fourteen PIs and NNRTIs in the anchor market. Guidelines from the U.S. Department of Health and Human Services ("DHHS Guidelines") confirm that PIs and NNRTIs are reasonably interchangeable as first-line therapy anchors combined with an NRTI-based backbone. Critically, Plaintiffs have not even attempted to demonstrate that Abbott has monopoly power in any product market defined to include more than just boosted PIs. Their antitrust claim fails for this reason alone.

b. Abbott Lacks Monopoly Power Even Under Plaintiffs' Improperly Defined "Boosted Market."

Even if a jury were to accept Plaintiffs' artificially-narrow Boosted Market definition as the relevant market, Abbott still would not have a "monopoly." "A mere showing of substantial or even dominant market share alone cannot establish market power sufficient to carry out a predatory scheme." (1/14/11 Order at 17.) Proving that Abbott has monopoly power requires evidence that it can "control prices or exclude competition." *Oahu Gas Serv., Inc. v. Pacific Resources Inc*., 838 F.2d 360, 366 (9th Cir. 1988) (quotation omitted). This generally requires at least a "sixty-five percent market share." (Order Granting in Part Abbott's Motion for Summary Judgment and Granting Plaintiffs' Cross-Motion for Summary Adjudication of Patent Invalidity at 10, *In re Abbott Labs. Norvir Antitrust Litig.*, Nos. C 04-1511 CW and C 04-4203 CW (May 16, 2008) (Docket No. 516); Order Denying Defendant's Renewed Motion for Summary Judgment at 10, *In re Abbott Labs. Norvir Antitrust Litig.*, Nos. C 04-1511 CW and C 04-4203 CW (July 6, 2006) (Docket No. 256) (citation omitted).) And even with a high market share—even well above 65%—the Ninth Circuit emphasized that, "[i]n evaluating monopoly power, it is not market share that counts, but the *ability to maintain market share*." *United States v. Syufy Enters.*, 903 F.2d 659, 665-66 (9th Cir. 1990) (emphasis added). In a case where the defendant's market share dropped from 93% to 75% in about three years, the Ninth Circuit emphasized that the district court "would do better to plot these

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[market share] points on a graph and observe the pattern they form than to focus narrowly on [defendant's] market share at a particular time." *Id* at 666.

Plotting market share points on a graph shows no monopoly power here. As discussed, even under GSK's narrow market definition, Abbott's market share dropped after Reyataz launched in mid-2003 from 100% to 81% in just six months, all before the Norvir price increase. Since then, Abbott's share has dropped all the way to 30%. No rival was excluded from the market—this is undisputed. Instead, rivals have dramatically increased their output and, in fact, have effectively taken over the market. The Ninth Circuit has held that judgment is warranted where, as here, the defendant lacked power to "restrict marketwide output and, hence, increase marketwide prices." *Rebel Oil*, 51 F.3d at 1434. Try as they might, the Direct Purchasers will not be able to change this result by manipulating data. They improperly double and triple count Abbott's prescriptions while single counting competitors' prescriptions (a topic explained in Abbott's *Daubert* motion on this subject).

Given Kaletra's precipitous market share decline (regardless of market definition), Plaintiffs will not be able to show that Abbott is dangerously close to obtaining monopoly power in that market. In fact, the opposite is true. Addressing a similar situation, the Second Circuit found that "[n]o reasonable jury could conclude from the rapid and continuous decline of [the defendant's] market share . . . that there was a probability that [the defendant] would monopolize the waffle market, let alone a dangerous probability." *Nifty Foods Corp. v. Great Atl. & Pac. Tea Co.*, 614 F.2d 832, 841 (2d Cir. 1980). Other courts have similarly found that a declining market share can prevent the plaintiff from showing a dangerous probability of obtaining a monopoly in the relevant market. *See Horst v. Laidlaw Waste Sys., Inc.*, 917 F. Supp. 739, 745 (D. Colo. 1996) (finding "that there is no probability of success in monopolizing the relevant market since [defendant's] market share actually decreased during the relevant time period"). This case is no different.

c. Plaintiffs Will Not Be Able To Show Barriers To Expansion And Entry.

Regardless of proper market definition and market shares, Plaintiffs will not be able to show monopoly power for an independent reason: there exist absolutely no barriers to expansion for

Abbott's multiple PI competitors. (*See* 1/14/11 Order at 17.) The definition of monopoly power is the ability to restrict marketwide output in order to support and maintain supracompetitive prices. *Rebel Oil*, 51 F.3d at 1434, 1441. Thus, "[e]ven a 100% monopolist may not exploit its monopoly power in a market without entry barriers. A § 2 plaintiff *must show* that new competitors face high market barriers to entry *and that current competitors lack the ability to expand their output to challenge a monopolist's high prices*." *Kodak*, 125 F.3d at 1208 (emphasis added) (citations omitted).

An alleged monopolist cannot command supracompetitive prices if, in response, a rival could simply increase its output of a competing product. "The ability to control output and prices—the essence of market power—depends largely on the ability of existing firms to quickly increase their own output in response to a contraction by the defendant. . . . [I]f rivals have idle plants and can quickly respond to any predator's attempt to raise prices above competitive levels, the predator will suffer an immediate loss of market share to competitors. In that instance, the predator does not have market power." *Rebel Oil*, 51 F.3d at 1441 (quoted in 1/14/11 Order at 18).

Plaintiffs cannot show that Abbott's competitors "are unable to expand their output in response to supracompetitive pricing" in the Boosted Market. *Id.* at 1438. If Abbott ever charged a supracompetitive price for Kaletra, rivals would simply respond by increasing their output of boosted PIs—which, under Plaintiffs' own market definition, are reasonably substitutable products—to erode Kaletra's market share. It costs very little for pharmaceutical companies to manufacture drugs, something this Court has noted costs only "pennies-per-pill." (Order Denying Abbott's Motion to Dismiss at 14 n.6, *Rite Aid Corp. v. Abbott Labs.*, No. C 07-6120 CW (Apr. 11, 2008) (Docket No. 41).)

The fact that the many other boosted PIs could expand their output, by itself, is enough to contravene any purported supracompetitive prices by Abbott. But additionally, competitors have entered, and will continue to enter, the Boosted Market, thus preventing Plaintiffs from showing sufficient barriers to entry. Since December 2003, two new boosted PIs have entered the market: Aptivus and Prezista. Although entry of new PIs certainly takes time and money, pharmaceutical companies are in the business of devoting both of those resources to creating new drugs. This fact

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further prevents Plaintiffs from proving monopoly power, or a dangerous probability of monopoly power.

B. Plaintiffs Cannot Show That Abbott's Conduct Was Exclusionary.

Even accepting Plaintiffs' Boosted Market definition and assuming that Abbott has monopoly power (which it does not), Plaintiffs will not be able to show that Abbott willfully maintained that power through exclusionary conduct. The Court has limited Plaintiffs' theories of exclusionary conduct to predatory pricing and a refusal to deal. (*See* 1/14/11 Order at 20-30.)

Importantly, to prove exclusionary conduct a plaintiff must prove an actual adverse market effect. As the Ninth Circuit made clear in *Rebel Oil*, "an act is deemed *anticompetitive* under the Sherman Act ***only*** when it harms both allocative efficiency *and* raises the prices of goods above competitive levels or diminishes their quality." *Rebel Oil*, 51 F.3d at 1433 (bolded emphasis added).[3] Even a "reduction of competition does not invoke the Sherman Act until it harms consumer welfare." *Id*. Thus, a key prerequisite to liability here is proof that Abbott had the ability to "raise[] the price[] of [Kaletra] above competitive levels" by excluding rivals and restricting marketwide output. *Id.* Indeed, low prices that eliminate rivals—even below-cost prices—are "of no concern to the antitrust laws" unless and until the alleged monopolist can charge "supracompetitive prices—prices above competitive levels" in the relevant market. *Id.* at 1433-34 (noting that "below-cost pricing is not anticompetitive in itself"); *see also Wallace v. IBM Corp.*, 467 F.3d 1104, 1106 (7th Cir. 2006) ("When exit does not occur, or recoupment is improbable even if some producers give up the market, there is no antitrust problem.").

As demonstrated below, Plaintiffs cannot show that Abbott's conduct, regardless of whether it is characterized as below-cost bundled discounting or a refusal to deal, allowed Abbott to restrict marketwide output such that it could sustain supracompetitive prices for Kaletra. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 233 (1993) ("Supracompetitive pricing entails a restriction in output."). Such conduct thus cannot be deemed "exclusionary."

[3] The concern with diminishing quality recognizes that a monopolist can effectively charge supracompetitive prices by maintaining the same price for a product while simultaneously lowering its quality. Plaintiffs, however, do not allege that Abbott diminished the quality of Kaletra. On the contrary, Abbott released a substantially improved formulation of Kaletra in 2005.

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1. Plaintiffs Cannot Show That Abbott's Pricing Conduct Fails The *Cascade* Safe Harbor.

Plaintiffs admit that Abbott has not priced Norvir or Kaletra below cost, and that the separate prices of those drugs are legal. Instead, Plaintiffs' claim is that Kaletra is a "bundle" of two separate products—Norvir and lopinavir according to Plaintiffs' prior statements, although the Court's recent summary judgment order speaks in terms of ritonavir and lopinavir—and that Abbott priced the bundle below cost under the "discount attribution" test adopted in *Cascade*. In that case, the Ninth Circuit established a safe harbor for bundled discounting if a plaintiff fails to prove that the "imputed" price of the competitive product in a bundle is below its cost. Even if Kaletra were a "bundle" subject to this test, Abbott's conduct still would satisfy this safe harbor.

Imputed price of lopinavir. For Plaintiffs to show below-cost pricing, the imputed price of lopinavir needs to be as low as possible and the price of the ritonavir in Kaletra needs to be as high as possible. So Plaintiffs inflate Norvir's price by ignoring what purchasers actually pay for the drug, and they rely on the price of a quantity of Norvir (200 mg) that was neither the most common boosting dose of Norvir nor even the average boosting dose of Norvir. Once these errors are corrected, the imputed price of lopinavir is well above its cost, no matter how it is measured.

Cost of lopinavir. After determining the imputed price for lopinavir, the next step is to compare this price to the average variable cost (AVC) of producing lopinavir. This AVC does not include fixed costs—*i.e.*, costs that do not change based on unit output, such as manufacturing equipment. The evidence will show that the cost of producing lopinavir is far below the imputed price of lopinavir, no matter how that price is measured.

Putting aside Plaintiffs' manipulation of the data to satisfy the discount attribution test, they have failed to explain how their predatory pricing theory makes sense. According to Plaintiffs, the price disparity between Norvir and Kaletra handicaps competitors, even as it does not entirely exclude them from the market. But by attempting to increase Kaletra's price to a supracompetitive level, Abbott would eliminate this price disparity and any effect it might have on restraining competition. Thus, Abbott can "'constrain[] the normal operation of the market'" only by keeping the price of Kaletra low in comparison to Norvir. *Kodak*, 125 F.3d at 1208 (quoting *Rebel Oil*, 51

F.3d at 1439). To sustain supracompetitive prices for Kaletra, Abbott must permanently and completely eliminate all (or, perhaps, virtually all) of its competitors from the market to prevent consumers from switching to rival PIs. In short, Plaintiffs must prove that Abbott has excluded the major competitors from the Boosted Market to restrict marketwide output such that it could *maintain* supracompetitive prices for Kaletra. Otherwise, Abbott's pricing is simply "of no concern to the antitrust laws." *Rebel Oil*, 51 F.3d at 1433. Regardless of whether the discount attribution test is satisfied, Plaintiffs have never made any effort to prove, and will not be able to prove at trial, that Abbott has "harm[ed] both allocative efficiency *and* raise[d] the prices of goods above competitive levels." *Id.* at 1433.

2. Plaintiffs Cannot Show That Abbott Essentially Refused To Deal Norvir.

This Court previously held that GSK must prove that Abbott "*essentially* refused to deal with competitors" by charging an "exorbitant" price for Norvir such that boosted PIs "could not compete with Kaletra." (1/12/10 Order at 12, 15 (Docket No. 195).) In its summary judgment ruling, the Court required Plaintiffs to prove that: (1) Abbott's pricing action terminated a voluntary and profitable course of dealing to sacrifice short-term profits in order to gain long-term monopoly profits; (2) Abbott charged such a high price for Norvir that boosted PIs, like Lexiva and Reyataz, could no longer compete with Kaletra; (3) Abbott refused to sell Norvir to competitors at a price it offered to direct purchasers and consumers; and (4) anticompetitive malice motivated any refusal to deal by Abbott with respect to Norvir. (1/14/11 Order at 27-30.) To attempt to meet that standard, Plaintiffs argue that Abbott effectively made Norvir unavailable for use with rival PIs because Norvir's new price amounted to an offer that HIV doctors and patients could not accept. At the same time that Abbott maintains that this claim fails as a matter of law for reasons discussed in previous briefing, Abbott also will show that Norvir is one of the top-selling HIV drugs. As discussed, Norvir sales have more than *quintupled* since the price increase. Thus, the jury simply will not be able to find an "effective" refusal to deal under these circumstances.

3. Abbott Had A Legitimate Business Justification For Its Pricing Conduct.

Even if Plaintiffs could show exclusionary conduct (which they cannot do), the jury still will not have evidence from which it could find Abbott liable under the Sherman Act because Abbott

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acted with a legitimate business justification. As discussed above, Abbott's witnesses and its contemporaneous records confirm that it raised Norvir's price to capture its new value—conduct entirely consistent with its patent rights.

As the Ninth Circuit has explained, "[w]hen a legitimate business justification supports a monopolist's exclusionary conduct, that conduct does not violate § 2 of the Sherman Act." *Kodak*, 125 F.3d at 1212; *see also* Erik Hovenkamp & Herbert Hovenkamp, *Tying Arrangements and Antitrust Harm*, 52 Ariz. L. Rev. 925, 960-63 (2010) (explaining that even "if a bundled discount flunks the [*Cascade*] attribution test and is thus considered exclusionary," the conduct may be justified by legitimate business reasons including "increased demand by those who used the primary good"). In particular, conduct designed to profit from a patented invention, including by charging a monopoly price in response to increasing demand for the product, is *pro*competitive and, thus, a legitimate business justification. As the Ninth Circuit made clear in *Kodak*, Abbott is "entitled to [charge] monopoly prices on its patented" Norvir. 125 F.3d at 1225; *see also id.* at 1218 n.11 (explaining that "Kodak is entitled to reap monopoly prices from the sale or licensing of" its patented products). Any contrary rule would "cut into the core rights conferred by patents" and frustrate the "fundamental and complimentary purposes of both the intellectual property and antitrust laws, which aim to encourage innovation, industry and competition." *Id.* at 1218 & n.11 (quotation omitted).

Because Abbott "assert[s] that its desire to profit from its intellectual property rights justifies its conduct, . . . the jury should *presume* that this justification is legitimately procompetitive." *Id.* at 1219 (emphasis added). Plaintiffs can rebut this presumption *only* by showing that Abbott's "proffered business justification *played no part* in the decision to act," or was "not a genuine reason for [Abbott's] conduct." *Id.* at 1219 (emphasis added). Plaintiffs may not "second guess" Abbott's business judgment by arguing that Abbott could have accomplished its goal of increasing its profits on Norvir sales through "less restrictive means." *Id.* at 1213, 1225. There simply is no way Plaintiffs can overcome this high bar to antitrust liability in this case.

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C. Plaintiffs Cannot Show A Specific Intent To Monopolize The Boosted Market.

To prove their attempted monopolization claim, Plaintiffs would also need to show that Abbott acted with a specific intent to monopolize the Boosted Market. As discussed above, Abbott increased Norvir's price to reflect increased demand for its booster properties, properties that Abbott never considered when originally pricing the drug. Abbott's documents, including its financial projections, absolutely refute the notion that Abbott intended to monopolize the Boosted Market.

D. Plaintiffs Cannot Show Antitrust Injury.

1. Plaintiffs Cannot Show That Abbott's Pricing Excluded Competitors And Resulted In Supracompetitive Pricing In The Relevant Market.

Even if Plaintiffs could show exclusionary conduct and monopoly power, they still would not be able to show antitrust injury. "To show an anti-trust injury, Plaintiffs must prove that their loss flows from an anti-competitive aspect or effect of Defendant's behavior." (Order Denying Defendant's Renewed Motion for Summary Judgment at 11, *In re Abott Labs. Litig.*, Nos. C 04-1511 CW and C 04-4203 CW (July 6, 2006) (Docket No. 256) (citing *Rebel Oil*, 51 F.3d at 1433).) The injury must actually be "attributable to an anti-competitive aspect of the practice under scrutiny" and must be "injury of the type the antitrust laws were intended to prevent." *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990) (quotation omitted). And it cannot be speculative. *Amarel v. Connell*, 102 F.3d 1494, 1507 (9th Cir. 1996). All members of the class must prove that they actually suffered antitrust injury. *See Eagle v. Star-Kist Foods, Inc.*, 812 F.2d 538, 541 (9th Cir. 1987); *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 534 (6th Cir. 2008).

Plaintiffs cannot meet their burden on this element either. There is no evidence that Abbott has excluded any, much less substantially all, Kaletra competitors. There is no evidence that output has been restricted in the Boosted Market. On the contrary, output has increased dramatically while rival PI prices have increased. And, there is no evidence that Kaletra is priced above competitive levels. The Supreme Court has squarely held that these precise facts cannot support a Section 2 claim: "Where, as here, output is expanding at the same time prices are increasing, rising prices are equally consistent with growing product demand. Under these conditions, a jury may *not* infer competitive injury from price and output data absent some evidence that tends to prove that output

was restricted or prices were above a competitive level." *Brooke Group*, 509 U.S. at 237 (emphasis added); *see also Omega Envtl., Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1164-65 (9th Cir. 1997) (reversing jury verdict on similar grounds). This binding authority stops Plaintiffs' case dead in its tracks.

2. Direct Purchasers Cannot Prove Any Overcharges.

The direct purchasers seek both purported Norvir "overcharges" and purported Kaletra "overcharges." Norvir overcharges are as a matter of law unavailable as damages here. Plaintiffs' claim for Kaletra overcharges falters based upon the evidence.

a. Direct Purchasers Cannot Prove Norvir Overcharges.

It is a "basic rule for antitrust damages" that "a purchaser may recover only for the price increment that 'flows from' the distortion of the market caused by the monopolist's anticompetitive conduct." *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 297 (2d Cir. 1979) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)); *see also Cascade*, 515 F.3d at 902 (explaining same rule). Regardless of whether Norvir overcharge "damages" would have been appropriate on Plaintiffs' boost*ing* market monopolization claim, the Court granted summary judgment on that claim. As explained in Abbott's relevant motion *in limine*, purported Norvir overcharges simply do not "flow from" any distortion caused by monopolization of the market in which Kaletra competes.

b. Direct Purchasers Have Not Properly Segregated Their Alleged Damages.

Even if Norvir "overcharge" damages somehow flowed from the competition-reducing effect of Abbott's purported misconduct—which plainly they do not, as explained in Abbott's relevant motion *in limine*—the Court still should exclude Norvir "overcharge" damages estimates. The Direct Purchasers have assumed a but-for Norvir price the same as, or similar to, the price before December 2003. Their experts have thus failed to account for the fact that only a *portion* of the disputed increased price allegedly violated *Cascade* or amounted to an "effective" refusal to deal.

The Ninth Circuit bars antitrust plaintiffs from recovering damages based, even in part, on lawful conduct. Antitrust plaintiffs must "segregat[e] between damages attributable to lawful

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competition and that attributable to the unlawful scheme." *Farley Transp. Co. v. Santa Fe Trail Transp. Co.*, 786 F.2d 1342, 1352 (9th Cir. 1985), *superseded on other grounds by* Fed. R. Civ. P. 50(b). As explained in Abbott's relevant motion *in limine*, Direct Purchaser experts Drs. Singer and Leffler include in some of their Norvir overcharge damages estimates even the portion of the Norvir repricing that are admittedly *lawful* under *Cascade*'s discount-attribution test. Even were Norvir "overcharge" damages available, they could not be based on the portion of the Norvir repricing that Plaintiffs concede would have been lawful under *Cascade*. *See* IIA Areeda, Antitrust Law ¶ 397g, at 432.

As further explained in Abbott's relevant motion *in limine*, the Direct Purchasers have also failed to segregate Norvir "overcharge" damages on their refusal to deal theory. They do not segregate the level of price increase that *would* amount to a purported "effective" refusal to deal from the level that would *not*. There is no legitimate basis for a damages theory that fails to segregate between the alleged unlawful and lawful aspects of the Norvir repricing.

c. Direct Purchasers Cannot Prove Kaletra "Overcharge" Damages.

The Direct Purchasers also claim they are entitled to damages for purported overcharges based on the pricing of Kaletra from 2005 to 2009. This claim will fail based upon the evidence. The increases in Kaletra's price during this period were in line with other relevant drug price increases; there is no evidence that they were above the competitive level. There also was no relevant change in the market that would explain why Abbott would or could take supra-competitive price increases in Kaletra during this time period when Abbott did not take them previously. On the contrary, the market continued to get more competitive since December 2003, as additional boosted PIs and other drugs were introduced and the number of prescriptions of the existing boosted PIs consistently increased. Furthermore, the largest of the Kaletra price increases that Plaintiffs challenge as "overcharges" occurred in October 2005 as part of Abbott's introduction of Kaletra tablets, which had many advantages for patients over the earlier Kaletra soft gel capsules.

Plaintiffs' claim for Kaletra overcharges also fails because, again, Plaintiffs' experts do not segregate any portion of the Kaletra price increases allegedly caused by anticompetitive conduct from the effects of lawful conduct. Dr. Singer bases his "but-for" Kaletra price estimate on the

conjecture that, but for any anticompetitive conduct by Abbott, the price of Kaletra would have remained the same from 2004 to 2009. Dr. Leffler assumes that the price of Kaletra would have increased at an annual inflation rate of a bit over two percent. Neither damages model is appropriate because neither justifies its assumptions.

d. Direct Purchasers Damage Claims Fail For Additional Reasons.

The Direct Purchasers' alleged damages fail for additional reasons, as specified in Abbott's motions *in limine* and as also to be developed at trial.

3. GSK Cannot Prove Any Lost Profits.

As discussed in more depth in Abbott's Omnibus Motion *In Limine*, as Abbott's expert Dr. Hay will explain at trial, GSK's expert Dr. Prowse has similarly failed to make any effort to "segregat[e] between damages attributable to lawful competition and that attributable to the unlawful scheme." *Farley*, 786 F.2d at 1352. Dr. Prowse devised a "lost profits" damages model estimating the profits that GSK lost on Lexiva due to the Norvir repricing. But in his computation, he improperly assumed that the antitrust laws prohibited Abbott from raising Norvir's price *at all*. Dr. Prowse's damages model thus fails to account for the fact that, even under Plaintiffs' theory, Abbott could have *lawfully* raised Norvir's price by a substantial margin. According to GSK's own expert Dr. Noll, repricing Norvir from $1.71 to $7.14 (instead of to the actual $8.57) would not have violated *Cascade*. But Dr. Prowse did not segregate GSK's purported losses resulting solely from the allegedly unlawful portion of the repricing. Compounding this error, Dr. Prowse included lost profits for *un*boosted Lexiva even though, according to GSK's own theory, unboosted Lexiva is not even in the relevant product market.

Dr. Hay will point out many additional flaws in Dr. Prowse's lost profits model. For example, Dr. Prowse relies solely on unreliable, pre-launch surveys and forecasts to estimate Lexiva's but-for market share that fail to address several important factors unrelated to Norvir's repricing that adversely affected Lexiva's performance—e.g., unfavorable results from Lexiva's clinical trials and Reyataz's clinical and commercial success. Indeed, the forecasts on which Dr. Prowse relied have been proven unreliable because they also inaccurately predicted market shares for drugs purportedly not affected by the Norvir repricing. Hay will also identify several

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methodological errors by Prowse that further inflate GSK's alleged lost profits, including his selective exclusion or marginalizing of lower and more reliable forecasts of Lexiva's market share prepared by the parties themselves.

Abbott's marketing and pricing expert Dr. Kolassa will explain, from the standpoint of a pricing and marketing expert, how the failure of Lexiva to live up to the expectations and plans of GSK was not caused by the repricing of Norvir. Instead, Lexiva's perceived underperformance was caused by at least three marketing failures—i.e., GSK's failures: (1) to recognize the shortcomings of Lexiva before its launch; (2) to recognize the true nature of a key competitor, Reyataz; and (3) to execute on key aspects of its own marketing plans.

III. GSK CANNOT SHOW THAT ABBOTT BREACHED THE LICENSE.

This Court has allowed GSK, based on Count 2 of its amended complaint, to "pursue a breach of contract claim for violation of 'any promise which a reasonable person in the position of the promisee would be justified in understanding were included'" in the parties' ritonavir license. (1/14/11 Order at 37 (citation omitted).) The evidence will not support a finding of breach, or compensable contract damages, much less treble damages under the UDTPA.

A. GSK Cannot Prove Contract Liability.

GSK concedes, as it must, that the license does not impose any restrictions on Abbott's ability to price Norvir. The negotiators will testify uniformly that these sophisticated parties intentionally *avoided* discussing Norvir's price during their negotiations. Indeed, several other drug companies entered into similar license agreements without such restrictions. Two such companies took ritonavir licenses *after*—and despite—the Norvir price increase. There is no way GSK can prove that a Norvir price limitation was integral to the parties' contract.

GSK nonetheless asserts that Abbott *implicitly* promised to allow GSK to increase sales of Lexiva by promoting it with Norvir. The agreement does not say this. But even accepting GSK's reading, Abbott has lived up to such a promise. GSK has continuously co-promoted Lexiva with Norvir worldwide since Lexiva's launch, without any effort by Abbott to enforce its ritonavir patents. This licensed right *has* allowed GSK to increase sales of boosted Lexiva, which otherwise would have been prohibited under the patent laws. Not only have those boosted Lexiva sales

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exceeded $1 billion, but GSK's percentage of boosted to unboosted sales even exceeded expectations set *before* the Norvir repricing.

The evidence will show that GSK is improperly attempting to read entirely new obligations into a contract by asking the jury to impose on Abbott an *implied* contractual obligation to refrain from pricing action that could adversely affect Lexiva sales. Abbott never agreed to constrain Norvir's price. It did *not* promise GSK any level of profitability with regard to Lexiva sales. And it certainly never agreed to stop competing with Lexiva. Under these circumstances, GSK could not have reasonably understood that Abbott was agreeing to constrain its pricing of Norvir.

B. GSK Cannot Prove Contract Damages.

Even assuming GSK could prove a contract breach (which it cannot do), GSK cannot prove any contract damages, much less an entitlement to treble damages.

Lost Profits. GSK cannot overcome the limitation of liability provision in the license, which the Court already held prohibits awards of lost profits. (1/14/11 Order at 40.) GSK will attempt to avoid this provision by showing that Abbott engaged in grossly negligent conduct that evinces intentional wrongdoing and a reckless indifference to the rights of others. Even if the jury were to find that Abbott breached an implied promise to constrain Norvir's price—a term the parties intentionally *avoided* during negotiations—GSK cannot show that such a breach evinces intentional wrongdoing. The notion that Abbott repriced Norvir to exclude Lexiva from the market is far-fetched, to say the least. Moreover, as explained above, Dr. Prowse's lost profits model is inherently biased, unreliable and cannot support a lost profits award in any event.

Restitution. As explained in Abbott's relevant motion *in limine*, GSK is barred as a matter of New York law from recovering restitutionary damages because it does not allege a "*total breach*" that effectively eliminated the value of contract. *Abdul v. Subbiah*, 735 N.Y.S.2d 29, 30 (N.Y. App. Div. 2001) (citing Restatement (Second) of Contracts § 373, cmt. a) ("[R]estitution is available ***only*** if the breach gives rise to a claim for damages for total breach and not merely to a claim for damages for partial breach." (emphasis added)). When GSK elected to retain the benefits of its license instead of ending the parties' agreement, "*[t]he consequence is that restitution is not available*, and [GSK] must pursue a claim for damages instead." *Old Stone Corp. v. United States*, 450 F.3d 1360, 1371

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(Fed. Cir. 2006) (quoting 13 Williston on Contracts § 39:32 (4th ed. 2000)); *see also* Restatement (Second) of Contracts § 236 (same). This makes sense. GSK cannot get its money back and still receive contractual benefits—that would be a windfall. *See* Restatement (Second) of Contracts § 384, cmt. a. GSK's theory that Abbott must *pay GSK* to grant GSK a license is truly absurd.

Even putting aside this fatal flaw in GSK's restitutionary damages theory, Dr. Hay will explain why GSK is entitled to no restitutionary damages based on the facts that will be established at trial. Dr. Hay will further explain how Dr. Prowse's restitutionary damages analysis has a number of methodological flaws and makes no logical or economic sense.

UDTPA. In its summary judgment ruling, the Court allowed GSK to pursue its claim for violation of North Carolina's Unfair and Deceptive Trade Practices Act only "to the extent it is based on Abbott's alleged breach of the implied covenant of good faith and fair dealing." (1/14/11 Order at 46.) But as this Court further explained, "[a] simple breach of contract, *even if intentional*, does not amount to a violation of the Act; a plaintiff must show substantial aggravating circumstances attending the breach to recover under the Act, which allows for treble damages." (*Id.* at 44-45 (emphasis added).)

Once again, GSK cannot even prove a breach of contract. Even if it could, at the very most any breach of the implied covenant of good faith and fair dealing here would be based on conduct that Abbott believed was permitted under the parties' contract. After all, all of the negotiators intentionally *avoided* reaching an agreement that would limit Norvir's price. As a result, GSK cannot possibly show Abbott "never had an intent to fulfill" the license agreement, much less that Abbott's conduct was "'unethical, oppressive, unscrupulous' and 'substantially injurious to consumers.'" (*Id.* at 45-46 (citation omitted).)

IV. CONCLUSION

For the foregoing reasons, the evidence will show that judgment should be entered in Abbott's favor and against Plaintiffs on all causes of action in their respective complaints.

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Dated: January 25, 2011

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